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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,308

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Thomas Jessel

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EXAMINER

GAMETT, DANIEL C

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

10/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/789,308	Applicant(s) JESSEL ET AL.	
	Examiner DANIEL C. GAMETT	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81,84 and 85 is/are rejected.
- 7) ☒ Claim(s) 82,83,86, and 87 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/27/2008 has been entered.
2. Claims 81-87, as amended on 02/27/2008 are under consideration.
3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.

Election/Restrictions

4. The restriction requirement of 08/15/2006 set forth eight groups of claims. In the response filed 02/21/2007, Applicants elected Group IV, Claims 66-79, drawn to methods for identifying a modulator of a Hh signaling pathway, and elected SHh from among the species of activators of a Hh signaling pathway recited in original claim 76. On 11/14/2007, Applicants cancelled the original claims and presented claims 81-87, which recite methods wherein embryonic stem cells are first contacted with retinoic acid and the resulting neural progenitor cells are then contacted with an activator of a Hh signaling pathway. These amendments were deemed to be consonant with the original election and were considered in the office action mailed 01/16/2008. Upon further inspection, it is also evident that if claims 81-87 had been present prior to the restriction requirement, they would have been recognized as species of

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generic method claims in Group I. This prompts a reconsideration of the patentable distinctness of original Groups I and IV. The restriction requirement of 08/15/2006 did not recognize that original claim 66 is generic to original claims 38 or 40, for example, with respect to the source of cells, but specific with respect to contacting cells with Hh, which is a species of the generic ventralizing factor recited in claims 38 and 40. Therefore, original groups I and IV are not patentably distinct. By the same reasoning, original groups I-IV should form a single generic group of systems and methods, and original groups V-VII should form a generic group of modulators, as follows:

- A. Claims 1-12, 14, 16-26, 28, 30-36, 38, and 40-79, drawn to an in vitro system and methods for identifying a modulator of neural differentiation, classified in class 435, subclass 377.
- B. Claims 13, 15, 27, 29, 37, 39, and 80 drawn to a modulator of neural differentiation, classification dependent upon the structure of the modulator.

5. This grouping would have comprised claims that are generic to patentably distinct species defined by the recitation of one or more of retinoic acid, BMP, Wnt, or an activator of a hedgehog signaling pathway, singly or in combinations in different method steps. Thus far, prosecution has proceeded as if Applicant has effectively elected a specific Group A method employing retinoic acid and an activator of a hedgehog signaling pathway. If the currently pending claims (or amended claims of similar scope) are found to be allowable, and if the restriction requirement of 08/15/2006 were left uncorrected, Applicants would be deprived of the opportunity to have generic claims and additional species examined. It is not possible to

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formulate a new restriction based on the currently pending claims that would reflect the species and linking claim relationships that existed in the original claims.

6. In view of the above, the restriction requirement between Groups I-IV set forth in the restriction requirement of 08/15/2006 is hereby withdrawn. Henceforth, any new claim that may be introduced will be considered as elected if it is generic to the currently pending claims and would have been grouped with any of original Groups I-IV. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

7. Likewise, the restriction requirement between Groups V-VIII set forth in the restriction requirement of 08/15/2006 is hereby withdrawn. This does not affect the instant case as these product claims were not elected. This withdrawal of restriction is made insofar as it may have a bearing on forthcoming divisional or continuation applications. Applicants are advised that the rejoined group of claims would comprise claims that are generic to patentably distinct species.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 81, 84 and 85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 7,390,659. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Both sets of claims are drawn to methods with the same steps; embryonic stem cells are first contacted with retinoic acid, a hedgehog pathway is activated, the cells are contacted with a candidate modulator (or “agent”), and a phenotypic response is determined. The instant claims recite measurement of a “feature characteristic of motor neurons”. In the patented claims, the phenotypic response is “growth”, which is defined as being indicated by features characteristic of motor neurons, such as size or thickness of the myelin sheath (col. 23, lines 32-67). Thus, the two sets of claims recite overlapping subject matter and are not patentably distinct.

Conclusion

10. Claims 81, 84, and 85 are rejected.

11. Claims 83, 84, 86, and 87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/
Examiner, Art Unit 1647